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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/541,082	04/07/2006	Jianjun Zhang	089889-000000US	4080

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TOWNSEND AND TOWNSEND AND CREW, LLP
TWO EMBARCADERO CENTER
EIGHTH FLOOR
SAN FRANCISCO, CA 94111-3834

EXAMINER	
HENRY, MICHAEL C	
ART UNIT	PAPER NUMBER
1623	
MAIL DATE	DELIVERY MODE
05/08/2007	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/541,082	ZHANG ET AL.	
	Examiner	Art Unit	
	Michael C. Henry	1623	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☐ Responsive to communication(s) filed on _____.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) 1-16 is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) 1-16 is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☒ All b)☐ Some * c)☐ None of:

1.☒ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date 10/31/05.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Claims 1-16 are pending in application

Priority

Receipt is acknowledged of papers submitted under 35 U.S.C. 119(a)-(d), which papers have been placed of record in the file.

Information Disclosure Statement

The information disclosure statement filed complies with the provisions of 37 CFR 1.97, 1.98 and MPEP § 609. It has been placed in the application file and the information referred to therein has been considered as to the merits.

DETAILED ACTION

Claims 1-9 are pending in application

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 1-5, 8, 9, 12, 13 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claims 1-5, 8, 9, 12, 13 provide for "A use of derivatives of succinate esters of general formula (I) ....., and the use of an extract of Coeloglossum ....." but, since the claims do not set forth any steps involved in the method/process, it is unclear what method/process applicant is intending to encompass. A claim is indefinite where it merely recites a use without any active, positive steps delimiting how this use is actually practiced.

Claim Rejections - 35 USC § 101

35 U.S.C. 101 reads as follows:

> Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title.

Claims 1-5, 8, 9, 12, 13 are rejected under 35 U.S.C. 101 because the claimed recitation of a use, without setting forth any steps involved in the process, results in an improper definition of a process, i.e., results in a claim which is not a proper process claim under 35 U.S.C. 101. See for example *Ex parte Dunki*, 153 USPQ 678 (Bd.App. 1967) and *Clinical Products, Ltd.* v. *Brenner*, 255 F. Supp. 131, 149 USPQ 475 (D.D.C. 1966).

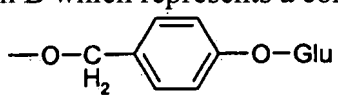
Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

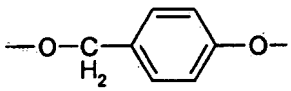
Claims 6, 7, 14-16 are rejected under 35 U.S.C. 102(b) as being anticipated by Kizu et al. (Chemical & Pharmaceutical Bulletin (1999) Vol. 47, No 11, pages 1618-1625).

In claim 6, applicant claims "A pharmaceutical composition, comprising an effective amount of any one of the compounds according to claim 1 and a pharmaceutically acceptable carrier. Kizu et al. disclose applicant's pharmaceutical composition, comprising the compound according to claim 1 and a pharmaceutically acceptable carrier (water) wherein the compound is dactylorhin B which represents a compound of formula (I) wherein

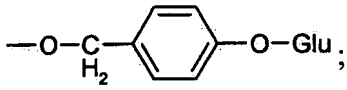
$R_1 = R_4 =$  ; R_2 = -O-Glu; R_3 = -OH and R_5 = isobutyl (a branched

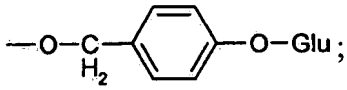
C_4 alkyl (see page 1621, compound (7) and page 1624, 2nd col., last paragraph). Kizu et al.'s pharmaceutical composition comprises a dactylorhin B (compound (7)) in H_2O (water) (see page 1624, 2nd col., last paragraph).

In claim 7, applicant claims "The pharmaceutical composition according to claim 6, characterized in that said pharmaceutical composition may be in the form of tablets, capsules, pills, injectable solutions, sustained released formulation, controlled released formulation and various microparticle systems. Kizu et al. disclose applicant's pharmaceutical composition characterized in that said pharmaceutical composition in the form of an injectable solution (see page 1624, 2nd col., last paragraph).

In claim 14, applicant claims "A pharmaceutical composition, comprising an effective amount of any one of the compounds according to claim 2 and a pharmaceutically acceptable carrier. Kizu et al. disclose applicant's pharmaceutical composition, comprising a compound according to claim 2 and a pharmaceutically acceptable carrier (water) wherein the compound is dactylorhin B which represents a compound of formula (I) wherein $R_1 = R_4 =$  ; R_2 = -O-Glu; R_3 = -OH and R_5 = isobutyl (see page 1621, compound (7) and page 1624, 2nd col., last paragraph). Kizu et al.'s pharmaceutical composition comprises a dactylorhin B (compound (7)) in H_2O (water) (see page 1624, 2nd col., last paragraph).

In claim 15, applicant claims "A pharmaceutical composition, comprising an effective amount of any one of the compounds according to claim 3 and a pharmaceutically acceptable carrier. Kizu et al. disclose applicant's pharmaceutical composition, comprising a compound

according to claim 3 and a pharmaceutically acceptable carrier (water) wherein the compound is dactylorhin B which represents a compound of formula (I) wherein $R_1 = R_4 =$  ; R_2 = -O-Glu and R_3 = -OH (see page 1621, compound (7) and page 1624, 2nd col., last paragraph). Kizu et al.'s pharmaceutical composition comprises a dactylorhin B (compound (7)) in H_2O (water) (see page 1624, 2nd col., last paragraph).

In claim 16, applicant claims "A pharmaceutical composition, comprising an effective amount of any one of the compounds according to claim 4 and a pharmaceutically acceptable carrier. Kizu et al. disclose applicant's pharmaceutical composition, comprising a compound according to claim 4 and a pharmaceutically acceptable carrier (water) wherein the compound is dactylorhin B which represents a compound of formula (I) wherein $R_1 = R_4 =$  ; R_2 = -O-Glu and R_3 = -OH (see page 1621, compound (7) and page 1624, 2nd col., last paragraph). Kizu et al.'s pharmaceutical composition comprises a dactylorhin B (compound (7)) in H_2O (water) (see page 1624, 2nd col., last paragraph).

Claims 10, 11 are rejected under 35 U.S.C. 102(b) as being anticipated by Huang et al. (Yaoxue Xuebao (2002), Vol. 37, No. 3, pages 199-203).

In claim 10, applicant claims "A pharmaceutical composition, comprising an effective amount of extracts according to claim 8 and a pharmaceutically acceptable carrier. Huang et al. disclose applicant's pharmaceutical composition, comprising an extract (of Coeloglossum viride (L.) Hartm. var.bracteatum (Willd.) Richter) according to claim 8 and a pharmaceutically acceptable carrier (ethanol) (see abstract). In claim 11, applicant claims "the pharmaceutical

composition according to claim 10, characterized in that said pharmaceutical composition may be in the form of tablets, capsules, pills, injectable solutions, sustained released formulation, controled released formulation and various microparticle systems. Huang et al. disclose applicant's pharmaceutical composition, comprising an extract (of Coeloglossum viride (L.) Hartm. var.bracteatum (Willd.) Richter) according to claim 10 and a pharmaceutically acceptable carrier (ethanol) in the form of an injectable solution (see abstract). It should be noted that applicant's claim to foreign priority over China 02159342.6 (12/21/2002) has not been perfected, since an English translation of the said foreign priority document is not filed.

It should be noted that although claims 1 and 8 (which recite a use of ...) were not examined, these claims also recite the prevention of dementia. However, it should be noted that in the future, for any claims that are examined and which recite the prevention of dementia, "the prevention of dementia" is not enabled and will be rejected as such.

Claim Objections

Claims 6, 7, 10, 11, 14-16 are objected to as being dependent upon a rejected base claim.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Michael C. Henry whose telephone number is 571-272-0652. The examiner can normally be reached on 8.30am-5pm; Mon-Fri. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Shaojia A. Jiang can be reached on 571-272-0627. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Michael C. Henry

5/3/07

Shaojia Anna Jiang, Ph.D.
Supervisory Patent Examiner
Art Unit 1623

May 1, 2007.